

REMARKS

In the Office Action dated November 30, 2007, the Examiner rejected claims 1-3, 9, 10, 11, 13-25, 28-29, 31-35, 38-40, and 49-50 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,293,921 to Shinmoto et al. ("Shinmoto"); rejected claims 4, 8, 36, and 41-43 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto; rejected claims 5-7 and 37 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto in view of U.S. Patent No. 4,738,668 to Bellotti et al. ("Bellotti(1)"); rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto in view of U.S. Patent No. 4,882,496 to Bellotti et al. ("Bellotti(2)"); and rejected claims 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto in view of U.S. Patent No. 4,655,753 to Bellotti et al. ("Bellotti(3)").

By this Reply, Applicant has amended claims 1, 2, 7, 8, 17, 29, 30, 33, 34, 41 and 50 and has cancelled claims 3-6 and 35-37. Accordingly, claims 1, 2, 7-34, and 38-50 are currently pending in this application. No new matter has been added by this Reply.

Independent claim 1 has been amended to recite, among other things, a "connecting device [that] further comprises means for providing a substantially sterile atmosphere in the inner space, said means for providing a substantially sterile atmosphere comprising a channel permitting an inward flow of a gas into the inner space, a filter arranged in said channel for filtering the gas before the gas enters the inner space, and a flow generator for providing said inward flow of gas through the channel, said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion."

Support for these claim amendments can be found in the specification at page 14, line 14 - page 15, line 5, for example.

Independent claim 29 has been amended to recite, among other things, a "connecting device [that] further comprises means for providing a substantially sterile atmosphere in the inner space, said means for providing a substantially sterile atmosphere comprising a channel permitting an inward flow of a gas into the inner space, a filter arranged in said channel for filtering the gas before the gas enters the inner space, and a flow generator for providing said inward flow of gas through the channel, said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion." Support for these claim amendments can be found in the specification at page 14, line 14 - page 15, line 5, for example.

Independent claim 33 has been amended to recite, among other things "providing a substantially sterile atmosphere in the inner space, providing, via a channel, an inward flow of a gas into the inner space, filtering the gas before the gas enters the inner space . . . wherein providing an inward flow of gas into the inner space occurs at least during connecting the first connection portion and the second connection portion and disconnecting the first connection portion from the second connection portion." Support for these claim amendments can be found in the specification at page 14, line 14 - page 15, line 5, for example.

REJECTION UNDER § 102(b)

In the Office Action, the Examiner rejected claims 1-3, 9, 10, 11, 13-25, 28-29, 31-35, 38-40, and 49-50 under 35 U.S.C. § 102 as being anticipated by Shinmoto. Applicant respectfully disagrees.

In order to properly anticipate Applicant's claims under 35 U.S.C. § 102, a single prior art reference must disclose each and every element of the claim at issue, either expressly or under principles of inherency. Further, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." See M.P.E.P. § 2131. Also, "[t]he elements must be arranged as required by the claim." Id.

Amended independent claim 1 recites, for example, a "connecting device compris[ing] means for providing a substantially sterile atmosphere in the inner space, said means for providing a substantially sterile atmosphere comprising a channel permitting an inward flow of a gas into the inner space, a filter arranged in said channel for filtering the gas before the gas enters the inner space, and a flow generator for providing said inward flow of gas through the channel, said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion."

Shinmoto discloses an "automatic exchanger apparatus . . . includ[ing] a housing which is opened and closed. The housing has three holders: the first holder for holding both the patient side connector and the first shut-off member . . . , the second shut-off member for holding both the bag side connector and the second shut-off member . . . , and the third shut-off member for holding the third shut-off member and its sealing member. . ." (Col. 4, lines 18-31.) Shinmoto also discloses that "[f]or carrying out the

connection and disconnection of the tubes under a sterilized condition, a sterilizing means using such as ultraviolet rays, ozone, heat, or microwaves may be provided in the housing of the automatic exchanger apparatus of the present invention. Also, it is a good idea to apply sterilizing agent to the ends of the tubes." (Col. 3 line 66 - col. 4 line 4.)

Shinmoto, however, does not disclose "a filter arranged in said channel for filtering the gas before the gas enters the inner space, and a flow generator for providing said inward flow of gas through the channel" (emphasis added) as recited in amended independent claims 1 and 29. In fact, the Examiner concedes that "Shinmoto does not disclose that the apparatus comprises a filter and flow generator that push a sterilizing gas to the interior of the connecting apparatus." (Office Action at 6.) Similarly, Shinmoto does not disclose "providing, via a channel an inward flow of a gas into the inner space, [and] filtering the gas before the gas enters the inner space" (emphasis added) as recited in amended independent claim 33.

For at least the aforementioned reasons, amended independent claims 1, 29, and 33 are allowable over the cited reference and the § 102(b) rejection of amended independent claims 1, 29, and 33 should be withdrawn. Further, dependent claims 2, 9, 10, 11, 13-25, 28, 31, 32, 34, 38-40, 49, and 50 (claims 3 and 35 having been canceled) are allowable over the cited reference at least due to their dependence from at least one of allowable independent claims 1, 29, or 33. Accordingly, the rejection of claims 2, 9, 10, 11, 13-25, 28, 31, 32, 34, 38-40, 49, and 50 should also be withdrawn.

REJECTIONS UNDER § 103(a)

In the Office Action, the Examiner rejected claims 4, 8, 36, and 41-43 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto. Applicant respectfully disagrees.

In the Office Action, the Examiner contends that “Shinmoto discloses that ozone or ultraviolet rays may be provided in the housing in order to sterilize the apparatus (see column 4, lines 1-4). As such Shinmoto suggests the channel (since gas cannot flow without some sort of channel) and disinfecting member claimed by applicant.” (Office Action at 5.) The Examiner concedes, however, that “Shinmoto does not disclose that the apparatus comprises a filter and flow generator that push a sterilizing gas to the interior of the connecting apparatus.” (Office Action at 6.)

Therefore, because Shinmoto does not disclose or suggest “a filter arranged in said channel for filtering the gas before the gas enters the inner space, and a flow generator for providing said inward flow of gas through the channel” (emphasis added), as recited in amended independent claims 1 and 29, or “providing via a channel an inward flow of a gas into the inner space, [and] filtering the gas before the gas enters the inner space” (emphasis added), as recited in amended independent claim 33, the Examiner’s contentions fail to cure the deficiencies of Shinmoto discussed above.

Accordingly, because claims 8 and 41-43 (claims 4 and 36 having been canceled) ultimately depend from at least one of independent claims 1 or 33, dependent claims 8 and 41-43 are allowable over the cited references and the § 103(a) rejection of claims 8 and 41-43 should be withdrawn.

In the Office Action, the Examiner also rejected claim 5-7 and 37 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto in view of Bellotti(1).

Bellotti(1) discloses a connector. The connector of Bellotti(1) "may have its usual bore or lumen for connection with the bore or lumen of another connector, plus first aperture means to serve as the antiseptic entry port for the abovedescribed [sic] process. This port will communicate between the exterior and the interior of the connector, and have the desired bacteria-blocking filter positioned therein. The first conduit connector also may have internal closure means for releasably sealing its interior without disrupting the sealing connection of it with another connector with which it mates. Thus a sterile connection area or sealed zone may be provided." (Col. 3, line 63 - col. 4, line 5.) Bellotti(1) further discloses that "[t]he chlorine gas or other desired preferably gaseous sterilizing material may be added from an ampule, particularly an ampule in which pressure is generated to force the gas into the system when desired. Alternatively, a syringe, squeeze bulb, or the like may be used." (Col. 4, lines 6-10.) Bellotti(1) also discloses that "[w]hen the chlorine gas has completed the sterilization process of the sealed zone area, ampule 40 may be removed, and hinged cap 32 may sealingly close over apertures 42 and 52." (Col. 7, lines 10-13.)

Bellotti(1) does not disclose "said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion" (emphasis added), as recited in amended independent claim 1.

Therefore, Bellotti(1) does not teach or suggest each element of amended independent claim 1. Accordingly, because claim 7 (claims 5, 6, and 37 having been cancelled) ultimately depends from amended independent claim 1, dependent claim 7 is

allowable over the cited references and the § 103(a) rejection of claim 7 should be withdrawn.

In the Office Action, the Examiner also rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto in view of Bellotti(2).

Bellotti(2) discloses an "[a]pparatus for disconnecting, sterilizing and making new tubing connection[s]." (Abstract.) The Examiner contends that Bellotti(2) discloses "a patient connector apparatus comprising a base 14 that holds connectors, enclosed by lid 12 in order to provide a sterile location for connecting the fluid lines (see FIG2, generally, column 4)." (Office Action at 7.)

Bellotti(2) does not disclose "said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion" (emphasis added), as recited in amended independent claim 1.

Therefore, Bellotti(2) does not teach or suggest each element of amended independent claim 1. Accordingly, because claim 12 ultimately depends from amended independent claim 1, dependent claim 12 is allowable over the cited references and the § 103(a) rejection of claim 12 should be withdrawn.

In the Office Action, the Examiner rejected claims 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Shinmoto in view of Bellotti(3).

Bellotti(3) discloses "[a] device [that] automatically uncouples two connectors and forms a new coupling between one of the connectors and another connector in a aseptic manner, without touch contamination from the user." (Abstract.) The Examiner

contends that "Bellotti discloses an aseptic tube connection apparatus that comprises an external handle 64 that is rotated by a user to engage gears inside the closed apparatus to move fluid connections in and out of communication with one another (see column 4, lines 41-50)." (Office Action at 7.)

Bellotti(3) does not disclose "said flow generator being capable of supplying said inward flow of gas at least during the connection of the first connection portion and the second connection portion and a disconnection of the first connection portion and the second connection portion" (emphasis added), as recited in amended independent claim 1.

Therefore, Bellotti(3) does not teach or suggest each element of amended independent claim 1. Accordingly, because claims 26 and 27 ultimately depend from amended independent claim 1, dependent claims 26 and 27 are allowable over the cited references and the § 103(a) rejection of claims 26 and 27 should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: July 11, 2008

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